NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

DRAFT
ACCREDITING AUTHORITY

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ACCREDITING AUTHORITY

6.0 ACCREDITING AUTHORITY

6.1 FOREWORD

NELAC (the National Environmental Laboratory Accreditation Conference) is a system for national standardization as a whole. State and Federal Accreditation Authorities that are members of NELAC participate in the development of National Standards through standing committees established by the respective NELAC to deal with particular fields of technical activity. NELAC technical and standing committees collaborate in fields of mutual interest.

This Section defines the NELAC Environmental laboratory accreditation systems - General recommendations for the acceptance of accreditation authorities, and, Testing laboratory accreditation systems - General recommendations for operation. It was drawn up by the NELAC Standing Committee on Accreditation Authority, on the basis of a draft transmitted by the National Environmental Laboratory Accreditation Conference and in collaboration with laboratory experts.

Its object is to provide definition for the setting up and operation of a Laboratory accreditation authority and to define NELAC acceptance of accreditation authority based on NELAC recognition. It is recognized that as a precondition for acceptance of an accreditation authority the authority must grant reciprocal recognition to all NELAC accepted authorities.

This section is organized based upon ISO/IEC Guide 25:1990, ISO/IEC Guide 58:1993 and ILAC Fourth Draft:1994. In some cases the names of major headings are slightly different than the referred to documents, however, the content of such sections meets the intent of the referenced documents. Where deemed necessary, specific areas within this section may contain more information than required by the international standards referred to.

This section defines the accreditation authority as the organization which is ultimately responsible for the accreditation system. The accreditation authority may choose to employee a public or non public organization to carry out some of its responsibilities in meeting this NELAC Standard requirements for accrediting laboratories. This organization is referred to as the accreditation body. It is recognized that some accreditation authorities will choose to utilizes accreditation bodies to aid in fulfilling their NELAC responsibilities. This section details what functions must be carried out and delineates those functions

which can be delegated to an accrediting body and what functions must remain with the accrediting authority.

Whilst NELAC Section 6 is intended to provide guidance, it is hoped that any additions to the documents made in introducing systems from the NELAC participating authorities would be minimal. In recognition of the fact that some authorities may choose to adopt the NELAC Standards directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory.

Environmental testing laboratory accreditation systems - General requirements for operation and recognition

6.2 SCOPE

This document sets out the general requirements for the operation of a system for accreditation of Environmental testing laboratories so that the accreditations granted and the services covered by the accreditations may be recognized at a national or an International level and the agency, operating the accreditation system may be recognized at national or International level as competent and reliable.

Users of the services of an accreditation body, other than the - laboratories accredited by the accreditation authority, may require compliance with requirements additional to those specified in this document. (See Section 1.8.2 on supplemental accreditation)

The object of this document is to provide guidance for the setting up and operation of an accreditation authority and to facilitate agreements on recognition of accreditation of laboratories between accreditation authorities and to define NELAC acceptance of accreditation authority based on NELAC recognition. It is recognized that as a precondition for acceptance of an accreditation authority the authority must grant reciprocal recognition to all NELAC accepted authorities.

NOTE - It is recognized that agreements on mutual recognition of accreditations aiming at the removal of barriers to across-border trade may have to cover other aspects not explicitly specified in these general requirements. To create confidence and harmonize the interpretation and implementation of standards, each accreditation authority should encourage technical cooperation and exchange of experience among laboratories accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation

authorities.

6.3 REFERENCES

NOTE : This section should be added to the APPENDIX B BIBLIOGRAPHY as References for Accreditation Authorities

ISO/IEC Guide 2:1991, General terms and their definitions concerning standardization and related activities.

ISO/IEC Guide 25:1990, General requirements for the competence of calibrations and testing laboratories

ISO/IEC Guide 43:1984, Development and operation of laboratory proficiency testing.

ISO 8402, Quality management and quality assurance - Vocabulary.

ISO 10011-1:1990, Guidelines for auditing quality systems-Part 1: Auditing

ISO 10011-2:1991, guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors.

6.4 DEFINITIONS

The relevant definitions contained in ISO/IEC Guide 2 are applicable. See APPENDIX A for this Standards Definitions.

6.5 ACCREDITATION AUTHORITY

6.5.1 General provisions

6.5.1.1 The procedures under which the accreditation Authority operates shall be administered in a non-discriminatory manner.

Access to an accreditation system operated by an accreditation authority shall not be conditional upon the size of the laboratory or membership of any association or group, nor shall there be undue financial conditions to restrict participation.

6.5.1.2 The competence of an applicant laboratory shall be assessed by the accreditation authority against all of the requirements of the requirements of the NELAC Standards.

6.5.1.3 The requirements of the NELAC Standards may have to be interpreted for a specific calibration or test by the accreditation authority. These interpretations shall be formulated by relevant and impartial committees or persons

possessing the necessary technical competence. They shall be published by the accreditation authority.

6.5.1.4 The accreditation authority shall require accredited laboratories to maintain impartiality and integrity.

6.5.1.5 The accreditation authority and accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

6.5.2 Organization of the accreditation authority

6.5.2.1 The accreditation authority shall

a) be a legally identifiable, public entity;

b) have rights and responsibilities relevant to its assessment activities;

c) have adequate arrangements to cover liabilities arising from its operations and/or activities;

d) have the financial stability and resources required for the operation of an accreditation assessment system;

e) have and make available on request a description of the means by which it receives its financial support;

f) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under a senior executive who is responsible to the organization, agency or board to which it reports;

g) have a quality system, including an organizational structure that enables it to give confidence in its ability to operate a laboratory accreditation assessment system satisfactorily;

h) have documented policies and procedures for the operation of the quality system that include:

-- policies and decision-making procedures that distinguish between laboratory accreditation assessment and any other activities in which the agency is engaged;

-- policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of

accreditation assessment matters, or from users of services about accredited laboratories or any other matters.

i) together with its program manager, and staff, be free from any commercial financial and other pressures which might influence the results of the accreditation process;

j) have formal rules and structures for the appointment and operation of committees involved in the accreditation assessment process; such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interests where no single interest predominates;

[Explainatory Note: Committees referred to here may be the NELAC Standing Committees]

k) establish one or more technical committees, each responsible, within its scope, for advising the accreditation authority on the technical matters relating to the operation of its accreditation system;

l) not offer consultancies or other services which may compromise the objectivity of its accreditation assessment process and decisions;

m) have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment and accreditation of laboratories.

[Explainatory Note: Committees referred to here may be the NELAC Standing Committees]

6.5.2.2 The accreditation authority shall have arrangements for either controlling the ownership, use and display of the accreditation documents or controlling the manner in which an accredited laboratory may refer to its accredited status, or both.

6.5.3 Quality system

6.5.3.1 The accreditation authority shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation authority staff. The accreditation authority shall designate a person having direct access to its highest executive level, to take responsibility for the quality system and the maintenance of the quality documentation.

6.5 3 2 The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

a) a quality policy statement;

b) the organizational structure of the accreditation authority;

c) the operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;

d) administrative procedures including document control;

e) policies and procedures to implement the accreditation assessment process;

f) arrangements for feedback and corrective actions whenever discrepancies are detected;

g) the policy and procedures for dealing with appeals, complaints and disputes;

h) the policy and procedures for conducting internal audits;

i) the policy and the procedures for conducting quality system reviews;

j) the policy and the procedures for the recruitment and training of assessors and monitoring their performance.

6.5.3.3 The accreditation authority shall audit its activities to verify that they comply with the requirements of the quality system. The quality system shall also be audited and reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective actions taken.

6.5.3.4 The accreditation authority shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

6.5.3.5 The accreditation authority shall have a policy and procedures for retaining records for a period consistent with its contractual and legal obligations. The accreditation authority

shall have policies and procedures concerning access to these records consistent with 6.6.2.1 (m) of this document.

6.5.4 Granting, maintaining, extending, suspending and withdrawing accreditation

6.5.4.1 The accreditation authority shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the laboratory's scope of accreditation. These conditions are defined in this NELAC Standard.

6.5.4.2 The accreditation authority shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require reassessment, in the event of changes affecting the laboratory's activity and operation, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the laboratory no longer complies with the requirements of the accreditation authority.

6.5.4.3 The accreditation authority shall have arrangements relating to the transfer of accreditation when the legal status (e.g. ownership) of the accredited laboratory changes.

6.5.5 Documentation

The accreditation authority shall provide (through publications, electronic media or other means), update at adequate intervals, and make available on request

a) information about the authority under which accreditation systems operated by the accreditation authority were established and specifying whether they are mandatory or voluntary;

b) a document containing its requirements for accreditation in accordance with the present document;

c) a document stating the arrangements for granting maintaining, extending, suspending and withdrawing accreditation;

d) information about the assessment and accreditation process;

e) general information on the fees charged to applicant and accredited laboratories;

f) a description of the rights and duties of accredited

laboratories as specified in 6.7.1,6.7.2 and 6.7.3 of this document, including requirements, restrictions or limitations on the use of the accrediting authority's logo and on the ways of referring to the accreditation granted.

6.6 LABORATORY ASSESSORS

6.6.1 Requirements for assessors

The assessor or assessment team appointed to assess a laboratory shall

a) be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements;

b) have a thorough knowledge of the relevant assessment method and assessment documents;

c) have appropriate technical knowledge of the specific tests or types of calibrations or tests for which accreditation is sought and, where relevant, with the associated sampling procedures;

d) be able to communicate effectively, both in writing and orally;

e) be free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to act in other than an impartial or non-discriminatory manner;

f) not have offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions.

NOTE - Guidance on personal attributes of assessors may be obtained from section 3.2.

6.6.2 Qualification procedures for assessors

The accreditation authority shall have an adequate procedure for

a) qualifying assessors, comprising an assessment of their competence and training, and attendance at one or more actual assessments with a qualified assessor, and

b) monitoring the performance of assessors.

6.6.3 Contracting of assessors

The accreditation authority shall require the assessors and/or the accreditation authority to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation agency, including those relating to confidentiality and those relating to commercial and other interests, and any prior association with laboratories to be assessed.

6.6.4 Assessor records

The accreditation authority and body shall possess and maintain up-to-date records on assessors consisting of

a) name and address;

b) organization affiliation and position held;

c) educational qualification and professional status;

d) work experience;

e) training in quality assurance assessment and calibration and testing;

f) experience in laboratory assessment, together with field of competence;

g) date of most recent updating of record.

6.6.5 Procedures for assessors

Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

6.7 ACCREDITATION PROCESS

6.7.1 Application for accreditation

6.7.1.1 A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited laboratories (including fees to be paid by applicant and accredited laboratories) shall be maintained up-to-date and given to applicant laboratories.

6.7.1.2 Additional relevant information shall be provided to

applicant laboratories on request.

6.7.1.3 A duly authorized representative of the applicant laboratory shall be required to sign an official application form, in which or attached to which

a) the scope of the desired accreditation is clearly defined;

b) the applicant's representative agrees to fulfil the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

c) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the laboratory.

[Explanatory Note: See Sections 4.1.9 and 4.1.7 for additional information]

6.7.1.4 The following minimum information shall be provided by the applicant laboratory prior to the on-site assessment:

a) the general features of the applicant laboratory (corporate entity; name, address, legal status, human and technical resources;

b) general information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, if applicable, physical location of laboratories involved;

c) a definition, for the calibrations concerned, of the type of measurement performed, the measurement range and best measurement capability, and for tests, of the materials or products tested, the methods used and the tests performed;

d) a copy of the laboratory's quality manual and, where required, the associated documentation.

The information gathered shall be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality

6.7.2 Assessment

6.7.2.1 The accreditation body shall appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

6.7.2.2 To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

6.7.2.3 The date of assessment shall be mutually agreed with the applicant laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the laboratory is given an opportunity to appeal against the appointment of any particular assessor.

6.7.2.4 The assessor(s) shall be formally appointed. A lead assessor shall be appointed, If relevant. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant laboratory.

[Explanatory NOTE - Guidance on procedures for assessment may be obtained in Section

4.1.2 ,and Section 3.0 .]

6.7.3 Sub-contracting of assessment

6.7.3.1 If an accreditation authority decides to delegate fully or partially the assessment of a laboratory to an accreditation body, then the accreditation authority shall take full responsibility for such an assessment made on its behalf.

6.7.3.2 The accreditation authority shall ensure that any accreditation body to which assessment has been delegated is competent and complies with the applicable provisions of this document and is a NELAC recognized accreditation body.

6.7.4 Assessment report

6.7.4.1 The accreditation authority may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that :

a) a meeting takes place between the assessor or assessment team and the laboratory management prior to leaving the laboratory, at which time the assessment team provides a written or oral report

on the compliance of the applicant laboratory with the accreditation requirements;

b) the assessor or assessment team provides the accreditation authority with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

c) a report on the outcome of the assessment is promptly brought to the applicant laboratory's notice by the accreditation authority, identifying any non-compliances that have to be discharged in order to comply with all of the accreditation requirements. The laboratory shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements identified during the assessment;

d) and other requirements of this NELAC Standard.

[Explanatory Note: See Sections 3.5 and 3.2.7]

6.7.4.2 The final report authorized by the accreditation authority and submitted to the laboratory, shall include as a minimum:

a) date(s) of assessment(s);

b) the name(s) of the person(s) responsible for the report;

c) the names and addresses of all the laboratory sites assessed;

d) the assessed scope of accreditation or reference thereto;

e) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements;

f) and other requirements of this NELAC Standard.

6.7.4.3 The reports should take into consideration:

a) the technical qualification, experience and authority of the staff encountered, especially the persons responsible for the technical validity of calibration certificates, test reports or test certificates;

b) the adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, and of the physical facilities, i.e.,the environment and the test equipment of the laboratory, including maintenance and calibration, having regard to the volume of work undertaken;

c) any proficiency testing or other interlaboratory comparison performed by the the applicant laboratory, the results of this proficiency testing, and the use of these results by the laboratory;

d) the actions taken to correct any non-compliances identified at previous assessments;

e) and other requirements of this NELAC Standard.

[Explanatory Note: See Section 3.0]

6.7.5 Decision on accreditation

6.7.5.1 The decision whether or not to accredit a laboratory shall be taken by the accreditation authority on the basis of the information gathered during the accreditation process according to 6.4.2.1

6.7.5.2 The accreditation authority shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

6.7.6 Granting accreditation

6.7.6.1 The accreditation authority shall transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of :

a) the name and address of the laboratory that has been accredited;

b) the scope of the accreditation, including:

1) the calibrations or tests, or types of calibration or test, for which accreditation has been granted;

2) for calibrations, the type of measurement performed, the measurement range and best measurement capability;

3) for tests, the materials or products tested, the methods used and the tests performed;

4) for specific calibrations and tests for which accreditation has been granted, the methods used defined by written standards or reference documents that have been accepted by the accreditation body;

c) the effective date of accreditation, and the term of the accreditation if applicable;

d) the accredited laboratory by a unique number;

e) and other requirements of this NELAC Standard.

[Explanatory Note: See Section 4.6]

6.7.7 Surveillance and reassessment of accredited laboratories

6.7.7.1 The accreditation authority shall have an established documented program consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with the accreditation requirements.

[Explanatory Note: See Section 4.3.2]

6.7.7.2 Surveillance and reassessment procedures shall be consistent with those concerning the assessment of laboratories as described in this NELAC Standard.

6.7.8 Proficiency testing

6.7.8.1 Laboratories shall be required by the accreditation authority to participate in proficiency testing as described in this NELAC Standard.

6.7.8.2 Proficiency testing may be organized by the accreditation authority itself or by any other agency judged competent. Proficiency testing should be consistent with the provisions contained in this NELAC Standard.

6.7.8.3 Accredited laboratories shall participate in proficiency testing or other interlaboratory comparisons as required by this NELAC Standard. Their performance in such tests shall meet the requirements of the NELAC Standard.

[Explainatory Note: See Sections 2.0 and 4.0]

6.7.9 Certificates or reports issued by accredited laboratories

6.7.9.1 An accreditation authority shall normally allow an accredited laboratory to refer to its accreditation in test reports that contain only the results of tests for which accreditation is held.

6.7.9.2 The accreditation authority shall have a policy that defines the circumstances in which accredited laboratories are permitted to include, in test reports the results of tests for which accreditation is not held and the results of sub-contracted tests.

6.8 RELATIONSHIP BETWEEN ACCREDITATION AUTHORITY, ACCREDITATION BODY AND LABORATORY

6.8.1 The accreditation authority shall have arrangements to ensure that the laboratory and its representatives afford such accommodation and cooperation as is necessary to enable the accreditation authority to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all calibration and testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.

6.8.2 The accreditation authority shall require that an accredited laboratory

a) at all times complies with the relevant provisions of this document;

b) claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

c) pays such fees as shall be determined by the accreditation authority;

d) does not use its accreditation in such a manner as to bring the accreditation authority into disrepute and does not make any statement relevant to its accreditation which the accreditation authority may consider misleading or unauthorized;

e) upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and returns any certificates of accreditation to the accreditation authority;

f) does not use its accreditation to imply product approval by the accreditation authority;

g) endeavors to ensure that no report nor any part thereof is used in a misleading manner;

h) In making reference to its accreditation status in communication media such as advertising, brochures or other documents, complies with the requirements of the accreditation authority.

6.8.3 Notification of change

6.8.3.1 The accreditation authority shall have arrangements to ensure that an accredited laboratory informs it without delay of changes in any aspect of the laboratory's status or operation that affects the laboratory's

a) legal, commercial or organizational status;

b) organization and management, e.g. key managerial staff;

c) policies or procedures, where appropriate;

d) premises;

e) personnel, equipment, facilities, working environment or other resources, where significant;

f) authorized signatories;

or other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria or competence specified by the accreditation authority.

6.8.3.2 Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the accreditation authority, the accreditation authority shall ensure that the laboratory carries out the necessary adjustments to its procedures within such time as, in the opinion of the authority, is reasonable. The laboratory shall notify the agency when such adjustments have been made.

6.8.4 Directory of accredited laboratories

The accreditation authority shall produce periodically a directory of accredited laboratories describing the accreditation granted.

6.9 RECOGNITION CRITERIA FOR AN ACCREDITING AUTHORITY BY NELAC

An accreditation authority or body will make application to NELAC by the following procedures. To be NELAC recognized an accreditation authority must be successfully audited by a NELAC team every two years.

6.9.1 Scope of Agreements

6.9.1.1 Except where an accreditation program is restricted to limited areas, it is expected that the NELAC recognition agreement will normally be comprehensive in nature.

6.9.1.2 It should be recognized however, that some NELAC recognition agreements may cover only subsets of scope.

6.9.2 Preparation for Evaluations

6.9.2.1 Once a decision has been made to proceed with negotiations for a NELAC recognition agreement and the scope to be covered, a number of preparatory steps are required. These include the need for exchange of a formal letter agreeing to pursue a recognition agreement and the need to set a timetable for evaluations. It will be necessary for formal applications to be submitted in accordance with the published policies and procedures of the NELAC to the office of the NELAP.

6.9.2.2 It will be necessary to confirm in writing the criteria which will be used in the evaluation process and these will normally be in terms of the current NELAC Standard. If there are additional criteria established for evaluations, these should be made clear to all parties.

6.9.2.3 Additional criteria used in evaluations for NELAC recognition agreements, include the following:

(a) The accreditation authority must be an operational, rather than a proposed system;

(b) The accreditation authority must have a minimum level of operational experience, such as reaching the stage of processing its first rounds of surveillance or monitoring visits to accredited laboratories;

(c) The accreditation authority must have a full-time program manager;

(d) The program manager of the accreditation authority or the senior support staff should have sufficient experience in the development or operation of a laboratory accreditation authority;

(e) The accreditation authority has granted a reasonable number of accreditations or performed a reasonable number of accreditation assessments;

(f) The accreditation system must have access to an appropriate measurement system that allows accredited laboratories to make

measurements that are traceable to national or international standards of measurement.

6.9.2.4 To prepare for an evaluation, the accreditation authority will need to provide background information on their accreditation program. Such background information will be required to be submitted with the formal application. This includes statements of the accreditation authority's operational status; its relationship to government and any statutory authority it has in laboratory accreditation; the accreditation criteria it uses; details of its staffing; the fields of accreditation in which it operates; and statistics on the numbers of accreditations granted and surveillance and reassessment details.

6.9.2.5 To prepare for formal evaluations for a NELAC recognition agreement, it will be necessary to provide major documentation relevant to the accreditation authority's' operations. This documentation includes:

(a) The accreditation authority's quality manual or other documentation which contains the policies and procedures of the accreditation authority and responsibilities for implementation;

(b) all technical criteria published by the accreditation authority;

(c) non-technical criteria published by the accreditation authority, including any formal rules or regulations affecting the accrediting authority's operation and the responsibilities and obligations of its accredited laboratories;

(d) any explanatory material describing the mechanics of operation of the laboratory accreditation system, including annual reports, questionnaires, newsletters, guidance documents, reports of proficiency testing programs, etc;

(e) full details of the composition and backgrounds of the full-time staff of the accreditation authority, including their years of experience in laboratory accreditation activities;

(f) a copy of the authority's directory or other listings of the names and scope of accreditation of all laboratories accredited by the authority;

(g) descriptions of any separate functions or affiliations of the authority to activities other than laboratory accreditation, (such as environmental sample analysis, product certification,

standards writing, etc);

(h) details of any formal recognitions or reciprocal agreements held by the authority either domestically or internationally, including recognition by government authorities, private sector organizations, other laboratory accreditation systems, etc;

(i) a statement of the accreditation authority's compliance with NELAC Standards, and any other specifications relevant to an agreement.

6.9.2.6 Where the accreditation authority subcontracts the task of assessment or other relevant activities to an accreditation body, the evaluation will need to include assessment of the roles of the accreditation body. Accordingly, any documentation of the type listed in 6.?.2.? which covers the subcontractors roles, should also be exchanged prior to an evaluation.

6.9.2.7 After collection and study of the above material, the NELAC assessment team will prepare a detailed program of the main activities which it requires to examine during an evaluation visit to the accreditation authority. The full content of this program is will be presented in that document.

6.9.2.8 The program and nominations of the various officers to be involved in an evaluation visit (together with any additional preliminary or clarifying questions) should be advised to the other party as soon as practicable and preferably at least one month before the proposed visit date.

6.9.2.9 For some NELAC recognition agreement groups, the selection of team leaders and team members for evaluations are described in their policies and procedures. Team leaders should be experienced staff members of NELAC accreditation authority's. Other team members may, where required, include experienced technical assessors.

6.9.2.10 Each evaluation team should prepare a set of briefing notes, checklists or questionnaires, detailing their understanding of the operation of various facets of the NELAC system (using the topics in this Standard and any other relevant guides or specifications), together with the specific questions which the agency wishes to raise about the area of the NELAC system's operation.

6.9.2.11 The availability of all key personnel needed for discussions during the period of a proposed evaluation visit, must be confirmed.

6.9.2.12 The size of an assessment team will vary, depending on the size and range of activities of the accreditation authority being assessed. Normally, there will be at least two people involved, and current practice for assessment of large, comprehensive authority's is to spend about 10-20 man days on evaluations. A typical assessment schedule is attached as Appendix D of this standard.

6.9.2.13 For smaller and special-purpose authorities, less time may be needed for evaluation and there may be an advantage in having a specialist assessor on the team with expertise relevant to the accreditation authority's scope of activity.

6.9.2.14 It is desirable, wherever possible, to include a member in the team with sufficient experience to evaluate the measurement support available to the system.

6.9.2.15 As part of the preparation, it will also be necessary to confirm the availability of suitable laboratory assessments and/or surveillance or reassessment visits to be witnessed during the course of an evaluation.

6.9.2.16 The accreditation authority being evaluated should be given the option to veto use of nominated members of the evaluation team.

6.9.3 Conduct of Evaluations

6.9.3.1 The objective of NELAC recognition agreements will be to determine that laboratories accredited by the accreditation authority are technically competent in the areas for which they are accredited and that the conduct of laboratory accreditation is in harmony with NELAC practice.

6.9.3.2 For the former aspect, technical competence, the overriding question is whether or not the accreditation authority's accredited laboratories would also achieve accreditation under NELAC's system.

6.9.3.3 For evaluation of harmony with NELAC practice, the basic criteria outlined in the NELAC Standard would be used by NELAC, and would include compliance with the NELAC Standard by laboratories accredited under the system being evaluated.

6.9.3.4 The audit will involve an initial appraisal of the documented procedures and policies used by the accreditation authority for their compliance with these NELAC criteria. This would be followed by evaluation of the implementation of those

procedures and policies, and appraisal of the effectiveness of the system's accreditation process to accredit technically competent laboratories that comply with the NELAC Standard and any other specified technical criteria.

6.9.3.5 The briefing notes, checklists or questionnaires referred to in Clause 6.9.2.11 of this document, should contain all the topics considered essential to be examined and appraised prior to and during a formal audit of the laboratory accreditation authority.

6.9.3.6 Evaluation against the NELAC Standard will require exercise of some judgment and perhaps interpretation as it is unlikely that each topic will be addressed in exactly the same way by different accreditation authority. What is required, is collection of sufficient detailed information on each topic to allow appraisal of the suitability of the practices used by the other party. Significant differences in approach between different authorities should not hinder recognition, but they should be highlighted, as they could affect the later preparation of the written NELAC recognition agreement.

6.9.3.7 The steps involved in conduct of an audit are:

(a) initial appraisal of the documented criteria; policies and procedures of the accreditation authority as set out in its quality manual, associated documentation and publications (normally conducted against the NELAC Standard);

(b) an on-site evaluation of the implementation of these policies and procedures;

(c) witnessing of conduct of laboratory assessments and/or reassessment and surveillance visits by the accreditation authority to judge whether the applicant and/or accredited laboratories are technically competent for the tests or calibrations for which they seek or hold accreditation. This component of the evaluation includes appraisal of the laboratories against the NELAC Standard and other technical criteria or interpretations of the NELAC Standard used by the accreditation authority.

6.9.3.8 After examination of documentation, the team leader should confirm the detailed program for evaluation and the availability of key personnel.

6.9.3.9 The team leader should then provide all team members with appropriate checklists, questionnaires and background information

on the accreditation authority and indicate specific aspects which should be evaluated by individual team members. Any standardized questionnaires and checklists used should be provided to all team members, prior to the audit.

6.9.3.10 The team leader should indicate to team members the overall division of work responsibilities to be used during the audit, together with appropriate estimates of time needed for these tasks, and the needs for, and timing of, any team meetings to be held throughout the course of the audit.

Opening Meeting

6.9.3.11 The on-site audit of the accreditation authority should commence with an opening meeting involving the senior management of the accreditation authority. Its purpose is to:

(a) confirm the objectives of the audit and the scope of activities to be covered;

(b) confirm the audit program including the on-site witnessing of laboratory assessments; and

(c) to make arrangements for reporting the outcomes of the audit (usually presented at an exit meeting (see Clause 6.9.3.2).

Administration Aspects of the Authority

6.9.3.12 The next stage of audit after the opening meeting will normally involve detailed evaluation of the administration of the authority. This involves a process of discussions and interviews with the full-time head of the program, and examination of the authority's implementation of its documented policies and procedures to determine compliance with the NELAC Standard. This would include evaluation of the following administrative elements:

(a) that the accreditation criteria of the agency include, at least, compliance of accredited laboratories with the NELAC Standard;

(b) the scope of the system;

(c) non-restriction of access to the system;

(d) the corporate or legal status of the accreditation authority;
(e) the financial stability, sources of funds and resources of the accreditation authority;

(f) the availability and backgrounds of technical staff;

(g) the organizational structure and responsibilities of individual staff;

(h) the effectiveness of the authority's quality system, including quality manual, documentation control, internal audits and quality system reviews and the role of the designated quality manager or officer;

(i) the roles of the governing authority and external committees and their relationships to the full-time head of the program;

(j) the procedures for the selection, training, contracting and appointment of assessors;

(k) the procedure for maintaining records of assessors and their usage;

(I) the procedures for making and processing applications;

(m) the procedures for preparation and issuing of assessment reports;

(n) the procedures for granting, maintaining, suspending, withdrawing and reinstating accreditations;

(o) the policy for preparation of accreditation schedules;

(p) the procedure for maintaining records of each applicant and accredited laboratory;

(q) the procedures for ensuring confidentiality by staff, assessors and external committees where applicable;

(r) the procedures for dealing with complaints and disputes;

(s) the availability of accreditation criteria documentation and assessment procedural documentation to technical staff of the accreditation authority and external assessors or experts;

(t) the procedure by which laboratories may appeal against the decisions of the accreditation authority;

(u) the relationships with technical and other organizations in the country;

(v) the existence and content of recognition agreements with other laboratory accreditation bodies;

(w) the conditions for the use of the authority's logo or reference to accreditation by the laboratory;

(x) the policies and procedures for use of proficiency testing data by the accreditation authority, for:

(i) proficiency tests conducted by the accreditation authority; and

(ii) proficiency tests conducted by other authorities (including any criteria for use of external programs).

(y) The policy for mandatory (or otherwise) involvement of accredited laboratories in proficiency testing programs;

(z) the policy on use of proficiency testing data for granting, or maintenance of accreditation.

Laboratory Evaluations

6.9.3.13 A major component of the evaluation will be the witnessing of conduct of assessments of laboratories by the accreditation authority. This should involve, wherever practicable, witnessing of both initial assessments of laboratories seeking accreditation and attendance at reassessment and/or surveillance assessments of laboratories already holding accreditation.

6.9.3.14 The purposes of witnessing assessments are to confirm that:

(a) the assessors are properly briefed to conduct assessments,

(b) that assessment teams are using the criteria and procedures of the accreditation authority (including appraisal against the minimum requirements of the NELAC Standard and any supplementary technical criteria); and

(c) that the assessment teams are effective in determining and recording/reporting the technical competence of laboratories for the tests for which accreditation is sought or held and are effective in identifying any noncompliances with the requirements for accreditation.

6.9.3.15 Normally, for a comprehensive system it will be desirable to witness at least three and preferably four assessments as part of an audit. This will normally mean that the audit team will need to split up to visit separate assessments during the course of an audit.

6.9.3.16 It is essential that the audit team members act as observers only during attendance at assessments. This is to avoid influencing the performance and procedures of the assessors and the responses of laboratory staff. Any of the audit team's observations on the assessed laboratories, the assessors or the accreditation authority's practices, should only be provided to the accreditation authority's representatives after the assessment.

6.9.3.17 Part of the appraisal of on-site assessments should include consideration of any guidance documents available for assessors, together with any supplementary criteria or rules needed to evaluate laboratories covered by the agency under

evaluation; or to determine assigned uncertainties of measurement etc.

6.9.3.18 If the accreditation authority's arrangements include appraisal of approved signatories or the use of measurement audit devices or other practical tests during assessments, these aspects should also be audited.

6.9.3.19 The roles and interactions of external assessors with any full-time assessors employed by the accreditation authority should also be evaluated in accordance with the documented procedures of the accreditation authority.

6.9.3.20 The audit team should also examine the procedures used to report the findings of assessment teams and to ensure that corrective actions are carried out within required time-scales.

Criteria Evaluation

6.9.3.21 Either before the on-site audit, or during the course of the audit, the team should examine the published accreditation criteria of the accreditation authority to establish whether it is sufficiently detailed to evaluate the technical competence of laboratories in the fields in which accreditation is available. This will include evaluation of the accreditation authority's criteria against the minimum requirements of the NELAC Standard, but will normally be expected to be supported by the availability of interpretations or supplementary criteria for specific fields of testing in which the authority operates.

Measurement Support

6.9.3.22 Traceability of calibrations to national or international standards of measurements is a fundamental requirement of the NELAC Standard. Traceability to the appropriate standards or access to other appropriate national standards should form a significant component of the evaluation. The use of accredited calibration laboratories by the testing laboratories covered by the authority should be examined in detail.

6.9.3.23 When traceability to national or international standards of measurement is not applicable, the team should check that laboratories are required to provide satisfactory evidence of correlation or accuracy of test results (for example, by participation in a suitable program of inter-laboratory comparisons or by the use of suitable reference materials).

6.9.4 Evaluation Findings and Report

6.9.4.1 The audit team should make provision in the visit program for time, while the team is together, to prepare a draft of the final report to be presented to the accreditation authority. This draft should be prepared from observations made and agreed by the team during the audit.

6.9.4.2 Normally, the team should prepare a short summary of the report indicating the main findings. This should be signed by all the team members and presented to the accreditation authority before departure.

6.9.4.3 The team leader should also present a more detailed verbal summary of the content of the final report to the accreditation authority at the final meeting at the end of the visit. The team leader should give the accreditation authority opportunity to comment on and discuss the teams findings and clear up any misunderstandings that may have arisen.

6.9.4.4 After the visit the audit team leader should complete the report and, subject to the approval of the final draft by the team members, submit it to the accreditation authority as soon as possible. It should highlight clearly any apparent non-compliances (as interpreted by the evaluation team) with the requirements of the NELAC Standard and the accreditation authority's own documented requirements.

6.9.4.5 The accreditation authority should be given the opportunity to correct any misunderstandings or errors appearing in the report.

6.9.4.6 The final report should be copied to all parties participating in the audit.

6.9.4.7 Appendix E provides an example format for an Evaluation Report.

6.9.5. Completing a Recognition Agreement

6.9.5.1 Before an agreement is finalized, it will be necessary for both parties under a proposed recognition agreement to respond formally on any actions resulting from the respective findings from the audit.

6.9.5.3 The final text of an agreement needs to be agreed between the recognition partners. For some agreements the text is standardized. Although each agreement may need to take into

account special circumstances, it is desirable that the text of recognition agreements between laboratory accreditation authorities and NELAC be as consistent as possible and Appendix C to this standard provides an example of the text of the existing agreement.

6.9.5.4 As a minimum, it is recommended that the text of NELAC recognition agreements include the following format:

(a) Purpose

Explaining the aim of the agreement

(b) Background

A brief description of the key features of the agency covered by the agreement.

(c) Understanding

A list of the obligations of the authority to the agreement with NELAC, normally declaring equivalence of confidence in the authority's implementation in its respective region; the willingness to promote authority acceptability of NELAC Standards; to resolve any differences between laboratories; to exchange information and literature etc.

(d) Name and Address of Parties

(e) Liaison Officers

Identifying the staff in the respective authority and NELAC who will be primary contact points for matters coming under the agreement.

(f) Period of Agreement

Four to five years is typical for existing agreements

(g) Appendix (Optional) - Comparison of Practices and Criteria

A summary analysis of the similarities and differences in practice of the authority to the NELAC Standard. (This could be an important component of some agreements - and is a recognition that although different techniques might be used for certain aspects of their operations, all parties accept that the end result is a comparable level of confidence in each system's operation).

6.9.6. Maintaining Agreements

6.9.6.1 After completion of a NELAC recognition agreement, it will be essential for NELAP to be kept informed of any significant changes in the operating practices or circumstances

of the accreditation authority. While much of this type of information may be transmitted in direct correspondence between the parties or through personal contact in a forum such as NELAC, there should be a structured approach to transfer of certain types of information.

6.9.6.2 Information which should automatically be transmitted to NELAP, includes:

(a) the authority's quality manuals and all technical criteria booklets, technical notes, nontechnical criteria or regulations, all policy statements or guidance notes for laboratories, and assessors;

(b) copies of directories of accredited laboratories and periodic updates;

(c) newsletters and annual reports, including annual accounts; and

(d) copies of typical summary reports of proficiency testing programs, particularly where laboratories in several sister NELAC member authorities are involved in a specific program.

6.9.6.3 In addition to the above published information the accreditation authority should ensure that NELAP is informed immediately if:

(a) there is a change in the name of the organization or its legal or corporate status;

(b) it enters into agreements with other parties or terminates agreements with other parties;

(c) its Head or key senior staff are replaced;

(d) there are any significant expansions into new areas of accreditation activity; or

(e) there are significant changes in the mode of operation of the authority, and particularly, the mechanisms for appraisal of laboratories.

6.9.6.4 Each agreement should nominate a contact person or liaison officer for transfer of information between the parties to an agreement, to ensure a consistent channel of communication.

6.9.6.5 If individual staff of NELAP or the authority

accreditation correspond with individuals in the other, normally a copy should also be sent to the liaison officer specified in the agreement, as some technical and administrative questions may require wider dissemination within the receiving organization.

6.9.6.6 For some scopes, it may be feasible to have joint participation in proficiency testing programs. These could be organized by either NELAP or the authority accreditation.

6.9.7. Formal Monitoring and Re-evaluations of Agreements

6.9.7.1 Once an agreement has been finalized and a pattern of regular interchange of information has been established, it will be necessary for periodic reviews to be conducted of the authority's system.

6.9.7.2 The period between re-evaluations should be agreed between the NELAP and the authority and stated in the agreement. (Typically agreements have set formal periods of four years between reviews). Earlier reviews may be appropriate if there are significant changes in the administration, finances, operational practices or scopes of accreditation coverage of the authority, or if there is a compelling reason to doubt the continuing effectiveness of the authority's program.

6.9.7.3 A formal re-evaluation should consider all of the aspects investigated during the negotiation of the initial agreement. Smaller teams may be required for the re-evaluation process. However, the same levels of seniority will apply to the staff used in re-evaluations. The authority should be willing to be subjected to re-evaluation at similar intervals.

6.9.7.4 Formal re-evaluations of the authority also provide an opportunity to review the usefulness of NELAP agreements. Accordingly, all authorities should attempt to collate information on the specific use of the agreement by laboratories and organizations in their respective regions for review at the NELAC. These experiences will then be shared during the re-evaluation process together with discussion of any significant problems arising out of an agreement or its implementation.

6.9.8 Other Issues

6.9.8.1 Authorities maintaining NELAP recognition agreements should establish whether there are any additional issues or requirements that may need to be considered when negotiating an agreement. Some of these other issues may include for example:

(a) the costs associated with conducting NELAP audits and the responsibilities of the authority for various costs;

(b) The respective policies of the authorities on accreditation of laboratories, particularly if they have accredited or intend to accredit laboratories in each other's regions

APPENDIX A

Typical Timetable for a comprehensive Authority Evaluation Visit (by a Team of at Least Two)

Before Visit

Authority's documentation is examined by team members and questions prepared.

Allocation is made of specific evaluation tasks to individual team members.

A team meeting is conducted before on-site assessment.

Day 1 At offices of accreditation authority presentations by team leader outlining aims, objectives and procedure to be adopted by audit team; background presentation on authority's operation by senior staff of accreditation authority; discussions with staff of accreditation authority on its administration, and its quality system and its implementation.

Day 2 Attendance as observers at laboratory assessment visit(s): typically one or two members of team at one laboratory with accreditation authority's assessors and two at another; or one team member at each of two assessments.

Day 3 Attendance as observers at laboratory reassessment or surveillance visit(s): typically one or two members of team at one laboratory with accreditation authority's assessors and one or two at another, or one team member at each of two reassessment or surveillance visits.

Day 4 Audit of authority's assessor training, measurement support and proficiency testing activities plus any administrative aspects not covered on Day 1.

Day 5 Completion of summary of report completion of draft final report* presentation and discussion of findings to accreditation authority at offices of accreditation authority*. Each evening the team should assemble at their hotel and discuss the day's findings as recorded on checklists and questionnaires and then prepare a draft report.

Post-evaluation

Team leader should complete the report, checking its accuracy with team members and submit it to the authority that has been

evaluated.

APPENDIX B

Contents of Audit Reports

It is recommended that audit reports follow a format similar to the following:

1. A cover page-identifying team leader, team members, dates of audit and organizations involved.

2. A summary page - prepared and signed by team members and handed over to the accreditation authority on the last day of the audit visit. This should contain the main conclusions and recommended actions needed to conclude an agreement.

3. An introduction-reason for audit, participants, criteria against which audit is performed, activities undertaken during audit, provision of documentation and translations, planning of laboratory visits and object of report.

4. A history of the accreditation authority under evaluation, including:

Relationship to government, responsibilities, management, numbers of accreditation, staffing levels and agreements with other authorities.

5. Observations on administration of system:

Covering compliance with the NELAC Standard. Comments should follow headings of NELAC Sections 6.1 -6.7.

6. Observations on the assessment of the authority's technical criteria (against the NELAC Standard and supplementary criteria) providing details of examination of the accreditation authority's technical criteria and guidance documents.

7. Observations on evaluation of the performance of assessors used by the system, including observations made at visits as compared with the NELAC Standard and on organization of visits, compliance by laboratories traceability in laboratories, non-compliance reporting and assessment reports.

8. Observations on use of proficiency testing by the accreditation authority.

9. Observations on measurement support, including the regional infrastructure available and its perceived effectiveness.

10. Where appropriate, compliance with any other standards in addition to the NELAC Standard.

11. Summary

12. Appendices

List of documents supplied before evaluation

Details of visit program

Miscellaneous material

APPENDIX C

Typical Content of a NELAC Recognition Agreement
Between Laboratory Accreditation Authority s and NELAC

1. Agreement

Accreditation Authority Recognition AGREEMENT

The Accreditation Authority denotes the {to be defined} who are responsible for operating accreditation systems for testing In {to be defined}.

The criteria for the operation of accredited testing laboratories and for the operation of the recognized accreditation authority are specified in the {to be defined}.

The cooperation of the NELAP for testing started formally In {to be defined} and is based on the NELAC Standards. An ongoing program of cooperation has been set up which is aimed at establishing confidence between authority's, so that agreements can be entered into that recognize the technical equivalence of the operation of their accreditation systems for testing laboratories.

This document sets out the terms of the Agreement in Section 1 and contains the signatures of the authorized representatives of NELAC and the Accreditation Authority that operate recognized laboratory accreditation systems for testing and are party to the Agreement.

RECOGNITION AGREEMENT

1. This Agreement is based on the results of the evaluations carried out in accordance with the NELAC Standard Section 6 Accreditation Authority.

2. The parties entering this Agreement are the accreditation authority in the {to be defined} and NELAC that have signed the Agreement on behalf of the accreditation systems for testing for which they are responsible.

3. On the basis of the equivalence of the operation of the Accreditation Authority, hereinafter also referred to as "System(s)", hereby declared, each signatory to this NELAP Agreement states that his/her agency will:

(I) recognize the operation of the other Systems by the accreditation authorities that are Signatories of this NELAP Agreement as equivalent to its own;

(II) recommend acceptance on an equal basis with those of its own accredited testing laboratories of the Test Reports and Test Certificates from the testing laboratories that are accredited by the other accreditation authorities that are Signatories to this NELAP Agreement;

(III) promote the acceptance of Test Reports and Test Certificates of accredited laboratories of Systems that are operated by the accreditation authorities that are Signatories to this NELAP Agreement by all users in its own state;

(IV) investigate all complaints by a Signatory to this NELAP Agreement resulting from Test Reports and Test Certificates issued by the accredited laboratories of its own System;

(V) notify all other Signatories as soon as possible of any significant changes that have or will occur in the status and/or operational practices of its own accreditation authority and System.

4. If a Signatory wishes to withdraw from this Agreement for any reason whatsoever, NELAP shall be notified in writing not later than six months in advance of withdrawing. Upon withdrawing of the accreditation authority, this Agreement shall be null and void.

6. Any amendment of the text of the Agreement shall be made in accordance with the rules of procedure of NELAC.

7. This Agreement consists of three pages and is signed on behalf of each participating recognized accreditation agency that operates a recognized accreditation system for testing laboratories.

8. This Agreement has come into force on {to be defined}.

9. SIGNATORIES

Authorized Representatives of Nationally Recognized Accreditation body responsible for operating NELAC and of the Accreditation Authority which are party to the Agreement.

{to be defined}

{to be defined}